

WHAT IS CLAIMED IS

1. A method of prevention or treatment of a cholesterol-associated tumor comprising
5 administering a therapeutically effective amount of an azetidinone-based cholesterol absorption inhibitor to a patient wherein the patient is either at risk of developing a cholesterol-associated tumor or already exhibits a cholesterol-associated tumor.

2. A method of prevention or treatment of a cholesterol-associated tumor according to
10 claim 1 wherein the azetidinone-based cholesterol absorption inhibitor is selected from the group consisting essentially of ezetimibe, SCH 48461 and SCH 58053.

3. A method of prevention or treatment of a cholesterol-associated tumor according to
claim 2 wherein the azetidinone-based cholesterol absorption inhibitor is ezetimibe or a
15 stereoisomeric mixture thereof, diastereomerically enriched, diastereomerically pure, enantiomerically enriched or enantiomerically pure isomer thereof, or a prodrug of such compound, mixture or isomer thereof, or a pharmaceutically acceptable salt of the compound, mixture, isomer or prodrug.

20 4. A method of prevention or treatment of a cholesterol-associated tumor according to claim 1 wherein the azetidinone-based cholesterol absorption inhibitor is selected from the group consisting essentially of ezetimibe, the phenolic glucuronide of ezetimibe, SCH 48461 and SCH 58053.

25 5. A method of prevention or treatment of a cholesterol-associated tumor according to claim 1 wherein the cholesterol-associated tumor is selected from the group consisting essentially of (benign prostatic hypertrophy, benign breast tumor, benign endometrial tumor, and benign colon tumor).

6. A method of prevention or treatment of a cholesterol-associated tumor according to claim 1 wherein the cholesterol-associated tumor is selected from the group consisting essentially of (malignant prostate tumor, breast cancer tumor, endometrial cancer tumor, and colon cancer tumor).

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7. A method of prevention or treatment of a cholesterol-associated tumor according to claim 5 wherein the azetidinone-based cholesterol absorption inhibitor is ezetimibe and/or at least one pharmacologically active analog thereof.

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8. A method of prevention or treatment of a cholesterol-associated tumor according to claim 6 wherein the azetidinone-based cholesterol absorption inhibitor is ezetimibe and/or at least one pharmacologically active analog thereof.

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9. A method of prevention or treatment of a cholesterol-associated tumor according to claim 7 wherein a therapeutically effective amount is between about 0.1 to about 30 mg/kg of body weight daily.

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10. A method of prevention or treatment of a cholesterol-associated tumor according to claim 8 wherein a therapeutically effective amount is between about 0.1 to about 30mg/kg of body weight daily.

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11. A method of prevention or treatment of a cholesterol-associated tumor comprising co-administering a therapeutically effective amount of an azetidinone-based cholesterol absorption inhibitor and at least one other anticancer agent to a patient wherein the patient is either at risk of developing a cholesterol-associated tumor or already exhibits a cholesterol-associated tumor.

12. A method of prevention or treatment according to claim 11 wherein the azetidinone-based cholesterol absorption inhibitor is ezetimibe and its analogs.

13. A method of prevention or treatment according to claim 12 wherein at least one other anticancer agent is selected from the group consisting of (a steroidal antiandrogen, a non steroidal antiandrogen, an estrogen, diethylstilbestrol, a conjugated estrogen, a selective estrogen receptor modulator (SERM), a taxane, and a LHRH analog).

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14. A method of prevention or treatment according to claim 13 wherein the non steroidal antiandrogen is selected from the group consisting essentially of (finasteride (PROSCAR®), flutamide (4'-nitro-3'-trifluoromethyl isobutyranilide), bicalutamide (CASODEX®), and nilutamide).

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15. A method of prevention or treatment according to claim 13 wherein the SERM is selected from the group consisting essentially of (tamoxifen, raloxifene, droloxifene, and idoxifene).

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16. A method of prevention or treatment according to claim 13 wherein the taxane is selected from the group consisting essentially of (paclitaxel (TAXOL®), and docetaxel (TAXOTERE®)).

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17. A method of prevention or treatment according to claim 13 wherein the LHRH analog is selected from the group consisting essentially of (goserelin acetate (ZOLADEX®), and leuprolide acetate (LUPRON®)).

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18. A composition for the prevention or treatment of a cholesterol-associated tumor comprising a therapeutically effective amount of an azetidinone-based cholesterol absorption inhibitor and at least one other anticancer agent.

19. A composition according to claim 18 wherein the azetidinone-based cholesterol absorption inhibitor is ezetimibe.

20. A composition according to claim 19 wherein at least one other anticancer agent is selected from the group consisting of (a steroidal antiandrogen, a non steroidal antiandrogen, an estrogen, diethylstilbestrol, a conjugated estrogen, a selective estrogen receptor modulator (SERM), a taxane, and a LHRH analog).

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21. A composition according to claim 20 wherein the non-steroidal antiandrogen is selected from the group consisting essentially of (finasteride (PROSCAR®), flutamide (4'-nitro-3'-trifluoromethyl isobutyranilide), bicalutamide (CASODEX®), and nilutamide).

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22. A composition according to claim 20 wherein the SERM is selected from the group consisting essentially of (tamoxifen, raloxifene, droloxifene, and idoxifene).

23. A composition according to claim 20 wherein the taxane is selected from the group consisting essentially of (paclitaxel (TAXOL®), and docetaxel (TAXOTERE®)).

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24. A composition according to claim 20 wherein the LHRH analog is selected from the group consisting essentially of (goserelin acetate (ZOLADEX®), and leuprolide acetate (LUPRON®)).

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25. An article of manufacture comprising a container, instructions, and a composition, wherein the composition comprises a therapeutically effective amount of an azetidinone²⁰ based cholesterol absorption inhibitor, and the instructions are for the administration of the composition for the prevention or treatment of a cholesterol-associated tumor.

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26. An article of manufacture according to claim 25 wherein the azetidinone-based cholesterol absorption inhibitor is ezetimibe and/or at least one pharmacologically active analog thereof.

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27. An article of manufacture according to claim 26 wherein the instructions are for the administration of the composition for the prevention or treatment of a tumor selected from the

group consisting of (prostatic hypertrophy (prostate tumor), breast tumor, endometrial tumor, and colon tumor).

28. An article of manufacture according to claim 26 wherein the composition further
5 comprises at least one other anticancer agent.

29. An article of manufacture according to claim 28 wherein at least one other anticancer
agent is selected from the group consisting of (a steroidal antiandrogen, a non-steroidal
antiandrogen, an estrogen, diethylstilbestrol, a conjugated estrogen, a selective estrogen receptor
10 modulator (SERM), a taxane, and a LHRH analog).

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